

## **Exhibit W**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Attorney Docket No. 780-A02-014-8  
Peter M. BONUTTI : Confirmation No. : 8298  
Application No.: 10/003,996 : Art Unit: 3733  
Filed: November 15, 2001 : Examiner: Mary C. Hoffman  
Title: *APPARATUS AND METHOD FOR TISSUE REMOVAL*

**RENEWED PETITION UNDER 37 C.F.R. §1.182 TO WITHDRAW**  
**A RECORDED TERMINAL DISCLAIMER**

Mail Stop: Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Dismissal of Petition, mailed on July 14, 2010, Applicant herein submits a renewed Petition.

Applicant hereby petitions for withdrawal of two Terminal Disclaimers under 37 C.F.R. §1.321(c), filed on March 31, 2003 and recorded on June 23, 2003, in the above-identified patent application.

The first of the two Terminal Disclaimers addresses the rejection of claims 36-40, 48, and 49 under obviousness-type double patenting over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317 and the second addresses the rejection of claims 36, 37, 39, 40, and 48 under obviousness-type double patenting over claims 1-9 of U.S. Patent 5,694,951.

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Statement of Case:

The above-identified application was filed on November 15, 2001 with forty-two claims, including, claim 1 of the parent application (U.S. Application Serial Number 09/483,676, filed on January 14, 2000) and claims 36-76 added by a Preliminary Amendment filed concurrently with the application. Claims 2-35 of the parent application were cancelled in the Preliminary Amendment. A copy of the claims as originally filed is attached hereto as Exhibit A.

The first Office Action was issued by Examiner Jessica R. Baxter on December 30, 2002 and included a first obviousness-type double patenting rejection as follows:

*Claims 36-40, 48, and 49 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a surgical procedure comprising removing tissue from a first location in a patient's body under the influence of suction by rotating a cutting tool, separating one or more components from at least a portion of the tissue removed by centrifugation, packing the tissue, adding a substance to the tissue after separating one or more components from the tissue, and implanting the tissue at a second location in the patient's body.*

A copy of the rejected claims 36-40, 48, and 49 and a copy of the cited patent claims 1, 5, 7, and 19-21 are attached hereto as Exhibits B and C, respectively.

The first Office Action also included a second obviousness-type double patenting rejection as follows:

*Claims 36, 37, 39, 40, and 48 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,694,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a surgical procedure comprising removing tissue from a first location in a patient's body under the influence of suction by rotating a cutting tool, separating one or more components from at least a portion of the tissue removed by centrifugation, packing the tissue, and implanting the tissue at a second location in the patient's body.*

A copy of the rejected claims 36, 37, 39, 40, and 48 and a copy of the cited patent claims 1-9 are attached hereto as Exhibits D and E, respectively.

The first Office Action also included further rejections of the claims and an indication of allowable subject matter in claims 41, 56, 71, 72, 75, and 76. A copy of the Office Action, a copy of U.S. Patent No. 5,403,317, and a copy of U.S. Patent No. 5,694,951 are attached hereto as Exhibits F, G, and H, respectively.

In response to the obviousness-type double patenting rejections, Applicant submitted two Terminal Disclaimers under 37 C.F.R. §1.321(c) with the Amendment filed on March 31, 2003.

The first Terminal Disclaimer stated, *inter alia*, the following:

*Petitioner hereby disclaims the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of U.S. Patent No. 5,403,317 issued on April 4, 1995.*

The second Terminal Disclaimer stated, *inter alia*, the following:

*Petitioner hereby disclaims the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of U.S. Patent No. 5,694,951 issued on December 9, 1997.*

A copy of the Amendment, a copy of the first Terminal Disclaimer, and a copy of the second Terminal Disclaimer are attached hereto as Exhibits I, J, and K, respectively.

Both of the Terminal Disclaimers were accepted and recorded as indicated at page 2 of the Office Action mailed on June 23, 2003. A copy of this Office Action is attached hereto as Exhibit L.

Despite the filing of the Terminal Disclaimers and the indication of allowable subject matter, prosecution continued and has been ongoing for nine years. The inaction of the Office contributed significantly to the delay. For example, responsibility for the case was supposedly transferred to a new Examiner after Examiner Baxter resigned from her position, however this transfer does not appear to have been timely as no substantive action was taken in the application from November 2004 to October 2006. This lapse in prosecution can be verified by the Transaction History obtained from PAIR on June 10, 2010, a copy of which is attached hereto as Exhibit M.

Claims 36-39, 41-44, 46, 47, 49, 57-60, 69-71, and 73-96, as now pending, have been indicated as allowable by Examiner Mary Hoffman. A copy of the current Office Action (mailed on April 15, 2010) and a copy of the pending claims are attached hereto as Exhibits N and O, respectively.

Upon notice of allowable subject matter, Applicant evaluated the necessity of the Terminal Disclaimers and on June 18, 2010 submitted two separate Petitions Under 37 C.F.R. §1.182 To Withdraw A Recorded Terminal Disclaimer. The first of the two Petitions addresses the rejection of claims 36-40, 48, and 49 under obviousness-type double patenting over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317 and the second addresses the rejection of claims 36, 37, 39, 40, and 48 under obviousness-type double patenting over claims 1-9 of U.S. Patent 5,694,951. A copy of each Petition is attached hereto as Exhibits P and Q, respectively.

Although two separate Petitions were filed, it appears that the Office entered only one as evidenced by the single entry "6-18-2010 Petition Entered" recorded in the Transaction History as obtained from PAIR on August 11, 2010, a copy of which is attached hereto as Exhibit R.

A Decision on Petition was issued by Petitions Officer John J. Gillon, Jr. on July 14, 2010. The Decision stated, *inter alia*, the following:

*The petition pursuant to 37 C.F.R. §1.182 is **DISMISSED**.*

The reference to a single Petition in the Decision and the lack of an additional Decision issued by the Office (of Petitions) further evidences that the Office (USPTO) entered and acted upon only one of the two Petitions submitted. A copy of the Decision is attached hereto as Exhibit S.

The filing of two Petitions can be verified by the File Wrapper as obtained from PAIR on August 11, 2010 and the separate Electronic Acknowledgement Receipt received for each of the two Petitions.

A copy of the File Wrapper, a copy of the Electronic Acknowledgement Receipt for the first Petition (Petition 317), and a copy of the Electronic Acknowledgement Receipt for the second Petition (Petition 951) are attached hereto as Exhibits T, U, and V, respectively.

Applicable Rules:

The basis for this petition is 37 C.F.R. §1.181-1.182. Rule §1.182 states, *inter alia*, the following:

*All situations not specifically provided for in the regulations of this part (§ 1.181, Petition to the Director) will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f).*

The procedure for withdrawal of a recorded Terminal Disclaimer (before issuance of patent) is discussed at section 1490 VII A of the MPEP.

Analysis:

In the interest of clarity and organization, Applicant has divided the “Analysis” section of this Petition into two parts, the first part establishing the reasons for requesting the withdrawal of the Terminal Disclaimers, and the second addressing the issues brought up by the Petitions Officer in the Decision on Petition.

Part One:

During prosecution of a patent application, the claim set can be, and usually is, altered in a variety of ways. Claims are amended, cancelled, added, and/or withdrawn. The scope of material encompassed by the claims is narrowed and/or expanded. As a result, allowed claims are often different, or at the very least somewhat evolved, from their original format. Considering the changes that can occur, Applicant can request that any double patenting rejection made early in prosecution be temporarily held in abeyance and subsequently reevaluated when the rejected claims are in allowable form. However, this practice is not etched in stone and any action taken to address a double patenting rejection is dependent upon the objectives of the Applicant at the time the action is to be taken.

In the instant case, Terminal Disclaimers were filed immediately in response to the rejection of claims 36-40, 48, and 49 over claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317 and the

rejection of claims 36, 37, 39, 40, and 48 over claims 1-9 of U.S. Patent No. 5,694,951. Applicant's reasons for this speedy filing are two-fold, desire to obtain an early allowance and desire to approach potential licensees with issued claims. These reasons are connected as a licensee is usually very happy with an early allowance and potential licensees view issued claims with more weight than potentially allowed claims.

The primary concern was the allowable subject matter indicated by Examiner Baxter (claims 41, 56, 71, 72, 75, and 76). Applicant reviewed the claims and decided that it would be prudent to pursue a quick allowance considering that obtaining allowable subject matter in an initial Office Action is rare. Furthermore, Applicant realized that arguing the merits of the double patenting rejection or requesting that it be held in abeyance would likely prevent a quick allowance or at the very least delay prosecution. Thus, without acquiescing to the necessity of the Terminal Disclaimers, Applicant filed the Terminal Disclaimers. In fact, at the time the Terminal Disclaimers were submitted, Applicant specifically stated:

In response and in order to expedite the prosecution of this application, Applicant submits herewith Terminal Disclaimers to obviate these double patenting rejections. It should be understood that these Terminal Disclaimers are being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimers are necessary.

Also of concern is the nature of the field. Medical technology, especially surgical technology, does not stand still. New methods, products, and procedures are continually developed and introduced to the market. Thus, surgical technology is an extremely active area in intellectual property. Efficient patent prosecution and quick allowance of claims are necessary in order to attract licensees for new products/methods and to provide any existing licensees with relevant products/methods. Such concerns further motivated Applicant to file the Terminal Disclaimers.

#### First Obviousness-Type Double Patent Rejection (U.S. Patent No. 5,403,317)

Claims 36-39 and 49, originally rejected under obviousness-type double patenting (the first rejection), are now allowable. Considering that these claims have been amended multiple times since the first rejection, Applicant has now evaluated the propriety of this obviousness-type double patenting rejection.

Claims 36-39 and 49 are distinguishable both from claims 36-40, 48, and 49 as initially rejected (under obviousness-type double patenting) and from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317.



Independent claim 36, as initially rejected, encompassed a surgical procedure to be conducted on a patient, the procedure comprising removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed (from the patient's body), and implanting the tissue at a second location in the patient's body after the components have been separated.

The steps of the surgical procedure, as now claimed in independent claim 36, have been expanded to include an additional step, *i.e.* packing the removed tissue into a desired shape after separating the components and prior to implanting at a second location. Additionally, the tissue removed is now further described as including blood and other body tissue. Thus, the scope of claim 36 as currently pending is distinguishable from the scope of the claim as initially rejected.

As does claim 36, independent claim 1 of U.S. Patent 5,403,317 encompasses a surgical procedure for removing and implanting tissue. However, claim 1 includes a step of compacting the tissue removed to decrease the volume of a mass of the tissue from a first volume to a second volume that is smaller than the first volume prior to implanting the tissue at a second location.

The step of "compacting tissue to decrease volume" involves consolidating or condensing tissue into a smaller form while the step of "packing tissue into a desired shape" involves arranging or collecting tissue but does not necessarily require that the volume of the tissue be decreased to be packed. Compacted tissue need not be shaped into any form. Further, a procedure including a step for packing tissue into a desired shape can be used in different clinical situations than a procedure in which tissue is compressed to fit into an opening or void. For example, tissue may be shaped to resemble bone and/or other body parts. Thus, from a comparison of the steps which distinguish the surgical procedure of claim 36 from the surgical procedure of patented claim 1; *i.e.* "packing tissue into a desired shape" vs. "compacting tissue to decrease volume", it is clear that the steps are neither identical nor mutually interchangeable within the surgical procedures. Accordingly, the step of packing tissue distinguishes the claims as currently pending from the patented claims.

Furthermore, claim 36, as currently pending, now specifies that the removed tissue to be packed includes blood and other body tissue. Blood contains the sticky clotting component fibrin and can be used to hold the tissue fragments together in the desired shape. There is no recitation in the patented claims that the tissue removed and compacted contains blood.

In addition to claims 1 and 7, patented claims 5 and 19-21 were cited in the obviousness-type double patenting rejection. Claims 5 and 19-21 require enclosing the removed tissue in biodegradable material (claim 5) or in a sac (claims 19-21). The rejected claims 36-39 and 49, as now pending, do not require any type of enclosure of tissue in biodegradable material or in a sac and are thus outside of the scope of the patented claims.

From the above discussion it is clear that claims 36-39 and 49 have changed in scope from claims 36-40, 48, and 49 as initially rejected, therefore the obviousness-type double patenting rejection is no longer applicable and should be withdrawn. Furthermore, it has been demonstrated that currently pending claims 36-39 and 49 are patentably distinguishable from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317, therefore the Terminal Disclaimer should be nullified.

#### Second Obviousness-Type Double Patenting Rejection (U.S. Patent No. 5,694,951)

Claims 36, 37, and 39, originally rejected under obviousness-type double patenting (second rejection), are now allowable. Considering that these claims have been amended multiple times since the first rejection, Applicant has now evaluated the propriety of the obviousness-type double patenting rejection.

Claims 36, 37, and 39 are distinguishable both from claims 36, 37, 39, 40, and 48 are initially rejected (under obviousness-type double patenting) and from claims 1-9 of U.S. Patent No. 5,694,951.

Independent claim 36, as initially rejected, encompassed a surgical procedure to be conducted on a patient, the procedure comprising removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed (from the patient's body), and implanting the tissue at a second location in the patient's body after the components have been separated.

The steps of the surgical procedure, as now claimed in independent claim 36, have been expanded to include an additional step, *i.e.* packing the removed tissue into a desired shape after separating the components and prior to implanting at a second location. Additionally, the tissue removed is now further described as including blood and other body tissue. Thus, the scope of claim 36 as currently pending is distinguishable from the scope of the claims as initially rejected.

As does claim 36, independent claims 1, 4, 7, and 8 of U.S. Patent No. 5,694,951 encompasses a surgical procedure for removing and implanting tissue. However in the patented claims the removing and transporting of tissue is accomplished via suction and a flow of fluid. Additionally, in patented claims 1, 4, and 7 tissue is moved to a collection location after removal from a first location in the patient's body and prior to implantation at a second location in the patient's body.

In the rejected claims 36, 37, and 39, tissue is removed from one location in a patient's body and implanted into a second location in the patient's body. The actual movement of the tissue between the locations does not necessarily require the use of suction and/or a flow of fluid. Furthermore, although the tissue is packed into a desired shape between the steps of removing and implanting, the tissue is not moved to any collection location. The patented procedure is suited to clinical situations in which the tissue is altered prior to implantation at the second location. For example, growth factors may be added to the tissue or diseased tissue can be removed and irradiated prior to implantation at the second location. Thus, from a comparison of the rejected claims with the patented claims, it is clear that the surgical procedures are distinguishable in at least two aspects; the manner in which the tissue is transported from the first location to the second location and the transfer of tissue to a collection location after removal from the first location and prior to implantation at the second location.

Furthermore, claim 36, as currently pending, now specifies that the removed tissue includes both blood and other body tissue. There is no recitation in the patented claims that the tissue removed and transported via suction/flow of fluid contains blood.

From the above discussion it is clear that claims 36, 37, and 39 have changed in scope from claims 36, 37, 39, 40, and 48 as initially rejected, therefore the obviousness-type double patenting rejection is no longer applicable and should be withdrawn. Furthermore, it has been demonstrated that the currently pending claims 36, 37, and 39 are patentably distinguishable from claims 1-9 of U.S. Patent No. 5,694,951, therefore the Terminal Disclaimer should be nullified.

Part Two:

On the first page of the Decision on Petition (Exhibit S), the Petitions Officer states, *inter alia*, the following:

*Buried, submarined, in one paragraph among approximately 114 pages of Petitioner's papers is the suggestion that Petitioner not only expressly requests withdrawal of a terminal disclaimer pursuant to 37 C.F.R. § 1.182, but also seeks outside of the appropriate rule a patent term extension.*

Applicant respectfully disagrees with this assessment of his intent. Neither of the previously-submitted Petitions includes a request for patent term extension. The introductory paragraph, setting forth the purpose for the Petition (Exhibits P and/or Q), states, *inter alia*, the following:

*Applicant hereby petitions for withdrawal of the Terminal Disclaimer under 37 C.F.R. §1.321 (c) filed on March 31, 2003 and recorded on June 23, 2003 in the above-identified application.*

There is no petition for patent term extension or mention of anything other than a Terminal Disclaimer. Thus, considering that the above is an introductory statement, Applicant's express intent to request only withdrawal of a Terminal Disclaimer is appropriately clear from the outset in the prior Petitions as well as in the current Petition which includes a similar introduction.

Patent term extension is not even mentioned until the Conclusion section:

*Applicant respectfully requests that the Terminal Disclaimer be withdrawn and any patent term extension to which he is entitled based upon delayed prosecution be granted.*

This statement is not, and should not be construed as, an express request for patent term extension, but rather as a request only for withdrawal of the Terminal Disclaimer such that the delayed prosecution caused by the inaction of the Office can be considered in the evaluation of patent term. Applicant did not, and had no intention to, inappropriately request both withdrawal of the Terminal Disclaimer(s) and grant of patent term extension in the same Petition.

As for "submarined" requests, each of the previously-filed Petitions, from introductory remarks to conclusion, consisted of only six pages. Although the Petitions did have attached exhibits, these exhibits added nothing further to the actual content (of the Petition) as the exhibits simply substantiated statements already made in the Petition. Thus, no clandestine requests are buried in "114 pages of Petitioner's papers."

The Petitions Officer asserts that there is a "history of conflict as to Petitioner's representations/intentions" and states, *inter alia*, the following:

*Moreover, Petitioner's discussion makes clear that Petitioner expressly determined as to prosecution strategy to submit the terminal disclaimer notwithstanding Petitioner's own beliefs that the disclaimer was unnecessary.*

Applicant disagrees. The Terminal Disclaimers were filed only to expedite prosecution, as is a common and acceptable practice for addressing rejection of claims under double patenting. See page 11, of Exhibit I, wherein Applicant explicitly states the following:

*It should be understood that these Terminal Disclaimers are being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimers are necessary.*

The necessity of the Terminal Disclaimers did not become a consideration until the end of prosecution when it was evident that the scope of the claims had evolved from the scope of the claims as originally rejected under double patenting. Accordingly, contrary to the belief of the Petitions Officer, there is no "history of conflict."

In the Decision, the Petitions Officer notes more than once that the Examiner in charge of this application has not concurred with the request for withdrawal of the Terminal Disclaimers. Although Applicant asserts that the Examiner's concurring with the request is irrelevant to grant of the Petition, Applicant's representative, Paul D. Bianco, spoke to the Examiner in the instant case, Examiner Mary Hoffman, on August 16, 2010, regarding the submission of the Petitions. Examiner Hoffman believes that she does not have the authority to make decisions regarding withdrawal of recorded Terminal Disclaimers.

Conclusion:

First, Applicant submits that this renewed Petition corrects the alleged deficiencies in the previously-filed Petition(s).

Since it is now established that allowed claims 36-39 and 49 are in fact patentably distinct from claims 1, 5, 7, and 19-21 of U.S. Patent No. 5,403,317 and allowed claims 36, 37, and 39 are also patentably distinct from claims 1-9 of U.S. Patent No. 5,694,951, Applicant respectfully requests that the Petition be granted and the recorded Terminal Disclaimers be withdrawn.

No fee is believed to be due for this Renewed Petition as the fees pursuant to 37 C.F.R. § 1.17(f) in the amount of \$400 were previously paid with the filing of the original Petitions. No other fees are believed to be due at this time. However, the Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account 503410.

Respectfully submitted,  
/Paul D. Bianco/

Date: August 18, 2010

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